

Official Use Only - Security-Related Information

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

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Amendment No. 86

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70 and 71, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		In accordance with letter dated February 15, 2024,	4. Expiration Date: August 31, 2039
1. St. Vincent's Medical Center			5. Docket No.: 030-01245 Reference No.: 06-30162-01
2. 2800 Main Street Bridgeport, CT 06606		3. License No.: 06-00843-03 is renewed in its entirety to read as follows:	
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As Needed	A. For use in uptake, dilution and excretion studies permitted by 10 CFR 35.100.
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As Needed	B. For use in imaging and localization studies permitted by 10 CFR 35.200.
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 500 millicuries total	C. For any use permitted by 10 CFR 35.300 for which the patient can be released under the provisions of 10 CFR 35.75.

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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

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|--|--|---|--|
| <p>6. Byproduct, source, and/or special nuclear material</p> <p>D. Iridium-192 permitted by 10 CFR 35.600</p> <p>E. Yttrium-90 permitted by 10 CFR 35.1000</p> | <p>7. Chemical and/or physical form</p> <p>D. Sealed Sources (Elekta, Inc. - formerly Nucletron [manufactured by Mallinckrodt Medical B.V., QSA Global, Inc., or Alpha-Omega Services, Inc.], Model 105.002)</p> <p>E. Microspheres (Sirtex Wilmington LLC [manufactured by Sirtex Wilmington LLC, Sirtex Medical Limited, or Sirtex Singapore Manufacturing Pte Ltd.], Model SIR-Spheres)</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>D. 12 Curies per source and 20 curies total</p> <p>E. 405 millicuries per source and 592 millicuries total</p> | <p>9. Authorized use</p> <p>D. One source for medical use permitted by 10 CFR 35.600, in a Nucletron B.V. Model microSelectron 106.990 HDR remote afterloader. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.</p> <p>E. For use in permanent manual brachytherapy using Sirtex Medical Limited SIR-Spheres Yttrium-90 microspheres and delivery system permitted by 10 CFR 35.1000.</p> |
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MATERIALS LICENSE SUPPLEMENTARY SHEET

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CONDITIONS

- 10. A. Licensed material listed in Subitem Nos. 6.A through 6.E may be used or stored at the licensee's facilities located at 2800 Main Street, Bridgeport, Connecticut.
- B. Licensed material listed in Subitem No. 6.B. may be used or stored at the licensee's facilities located at the St. Vincent's Regional Heart and Vascular Center, 2979 Main Street, Bridgeport, Connecticut.
- C. Licensed material listed in Subitem Nos. 6.A. and 6.B. may be used or stored at the licensee's facilities located at 32 Knight Street, Norwalk, Connecticut; 1177 Summer Street, Stamford, Connecticut; and 205 Sub Way, Suite 101, Milford, Connecticut.

11. The Radiation Safety Officer (RSO) for this license is Gregory Hisel, CHP.

12. Licensed material shall only be used by, or under the supervision of:

- A. Individuals permitted to work as authorized users and/or authorized medical physicists in accordance with 10 CFR 35.13 and 10 CFR 35.14.
- B. The following individuals are authorized users for the material and medical uses as indicated:

Authorized Users

Material and Use

Venu Channamsetty, M.D.

10 CFR 35.100, 10 CFR 35.200

Steven M. Cohen, M.D.

10 CFR 35.100, 10 CFR 35.200; 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131)

Thomas DiBartholomeo, M.D.

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300; 10 CFR 35.1000 (limited to Yttrium 90 SIR-Spheres)

Terence W. Hughes, M.D.

10 CFR 35.1000 (limited to Yttrium 90 SIR-Spheres)

Christopher M. Ianuzzi, M.D.

10 CFR 35.300 (limited to the parenteral administration of unsealed byproduct material); 10 CFR 35.600 (limited to Iridium 192 in a High Dose Rate Remote Afterloader Unit)

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Authorized Users

Robert D. Jumper, M.D.

Ian G. Karol, M.D.

Adam Kaye, M.D.

Greg B. Marrinan, M.D.

Gerard J. Muro, M.D.

Thomas D. Olsavsky, M.D.

Alon Ronen, M.D.

Eran Rotem, M.D.

Robert D. Sackstein, M.D.

Craig S. Werner, M.D.

Scott C. Williams, M.D.

Deborah Ziangdong Fang, M.D.

Kenneth M. Zinn, M.D.

Material and Use

10 CFR 35.100, 10 CFR 35.200

10 CFR 35.100, 10 CFR 35.200; 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131 for imaging and localization studies)

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

10 CFR 35.100, 10 CFR 35.200

10 CFR 35.100, 10 CFR 35.200; 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131 for imaging and localization studies)

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

10 CFR 35.200

10 CFR 35.1000 (limited to Yttrium 90 SIR-Spheres)

10 CFR 35.200

10 CFR 35.200

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

10 CFR 35.300 (limited to the parenteral administration of unsealed byproduct material); 10 CFR 35.600 (limited to Iridium 192 in a High Dose Rate Remote Afterloader Unit)

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

C. The following individuals are authorized medical physicists for the materials and uses as indicated:

Authorized Medical Physicist

Qing Chen, M.S.

Nicholas A. Mongillo, M.S.

Theodore R. Steger III, Ph.D.

Material and Use

Iridium 192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training

Iridium 192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training

Iridium 192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training

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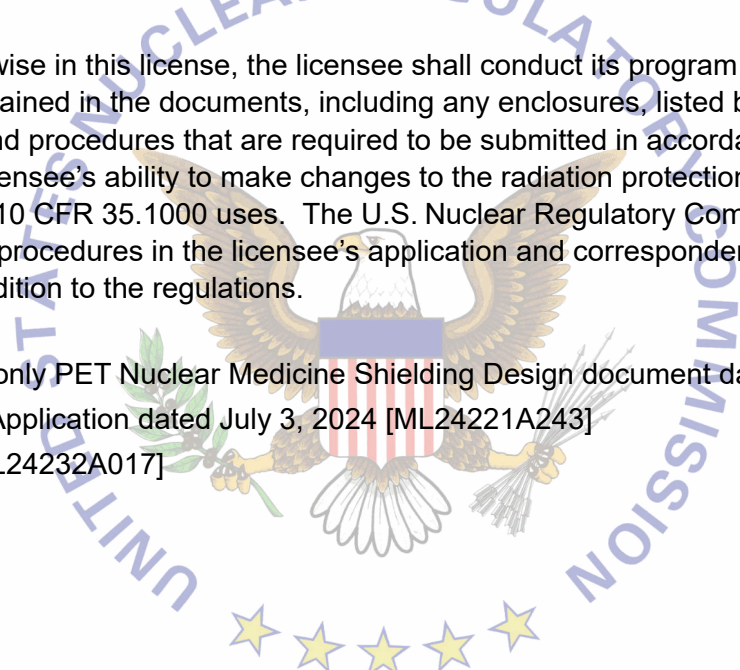
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- 13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit in 10 CFR 30.35(d) for which decommissioning financial assurance is required.
- 14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those statements, representations, and procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26 and applicable guidance updates for 10 CFR 35.1000 uses. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence impose on the licensee requirements that are more restrictive than or in addition to the regulations.
 - A. Letter dated February 15, 2024, only PET Nuclear Medicine Shielding Design document dated 7/29/2008 [ML24058A201]
 - B. Letter dated July 12, 2024, with Application dated July 3, 2024 [ML24221A243]
 - C. Letter dated August 16, 2024 [ML24232A017]



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: August 19, 2024

By: _____
Robin Elliott
Region 1